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NISBET, T EXAMINER

ART UNIT	PAPER NUMBER
1806	37

DATE MAILED: 11/01/94

VICKI S VEENKER
FISH & NEAVE
1251 AVENUE OF THE AMERICAS
NEW YORK NY 10020

18M2/1101

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 6/27/94 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire three month(s), ~~days~~ from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 39-41, 43-48, 54-55, 57-58, 60-69, 71-95 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 52, 53, 56, 59, 70 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 39-41, 43-48, 54-55, 57-58, 60-69, 71-95 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

III. DETAILED ACTION

15. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

16. The filing of new claims 78-95 in the amendment filed 6/27/94 is acknowledged.

17. Applicant's limitation of the claims to recite the production of antibodies in lymphoid cell lines obviates the rejection under § 112. In addition, applicant's explanation of the apparent inconsistencies in the 131 declaration are sufficient. The fact that the reagent was replaced and the experiments were subsequently successful establishes that the said success was reproducible. Accordingly, said rejection is withdrawn.

18. Claims 39-41, 43-48, 54-55, 57-58, 60-69, and 71-95 are rejected under 35 U.S.C. § 103 as being unpatentable over Cabilly (L,R, or 2A) or Boss (2b) in view of Gillies(S).

Applicant's arguments filed 6/27/94 have been fully considered but they are not deemed to be persuasive.

Rejections are maintained for reasons of record, stated in papers 5, 7, and 10, mailed November 29, 1988, May 24, 1989, and September 25, 1990.

The amendment and response filed 6/27/94 set forth the following grounds of traversal. The first asserts that insufficient predictability existed at the priority date to allow coexpression of two antibody chains. Applicants urge that the Cabilly references do not have a teaching of specific coexpression of genes in a mammalian system and that Cabilly's yield was not nearly as good as that in the instant case. Gillies is criticized for the alleged failure to actually show functional antibody. In addition, the Gillies patent allegedly fails to asses the yeild of a functional antibody. Only raw, unassembled protein is shown.

These arguments have been considered but are not deemed persuasive. The argument concerning Cabilly is not considered persuasive because of the aforementioned specific teaching of producing antibodies in mammalian cells. While applicants are correct in characterizing Cabilly's disclosure as non-enabling for myeloma cell production, Cabilly is only used to teach double transfection. Gillies shows the production of antibodies in myeloma cells. Morover, Gillies teaches the production of proteins in a yeilds approaching wild type. Therefore, such yields are considered approximating 100% in comparison to applicant's 32%. Accordingly, applicant's argued unexpected yields are not considered as such. As far as applicant's -

regarding the fact that Gillie's yield is of unassembled protein, such is simply not supported by Gillies. Applicants have not pointed out the statement in Gillies where the routineer would learn that Gillies' protein is not assembled. Absent such a clear disclosure to the contrary, it is more reasonable to assume that Gillies' disclosed yield is functional. Ohterwise, Gillies would not be producing the protein. The protein/antibody is of no use when it is not functional. Accordingly, Applicants' the rejection is maintained and no claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Nisbet whose telephone number is (703) 308-4204 from 9:00 am to 5:00 pm weekdays with the exception of alternating Fridays. If the examiner cannot be reached, the supervisor may be contacted at phone number (703)308-3535.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

TMN
October 31, 1994

DAVID L NISCEY
SUPERVISORY PATENT EXAMINER
GROUP 130

10/31/94